

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant:	STEVEN E. WALAK	Confirmation No.:	3380
Serial No.:	10/725,890	Examiner:	Bradley J. Osinski
Filing Date:	DECEMBER 2, 2003	Group Art Unit:	3767Q
Docket No.:	1001.1632101	Customer No.:	28075
Title:	COMPOSITE MEDICAL DEVICE AND METHOD OF FORMING		

**REPLY BRIEF UNDER 37 C.F.R. § 41.41**

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Dear Sir:

Pursuant to 37 C.F.R. § 41.41, Appellant hereby submits this Reply Brief in furtherance of the Appeal Brief filed on September 5, 2008 and the Examiner's Answer of November 21, 2008.

### **STATUS OF CLAIMS**

The status of claims is as set forth in the Examiner's Answer of November 21, 2008, namely:

Claims 1-22, 25-70 and 73-75 are pending in the application, of which, claims 28-56 are withdrawn. Claims 23-24 and 71-72 have been canceled from the application.

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter "Ren"), in view of *Viera*, U.S. Patent 6,039,699.

Claims 12, 17, 60 and 65 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184.

Claims 14 and 62 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105 (hereinafter "Rooney").

Claims 74 and 75 stand allowed.

Claims 1-22, 25-27, and 56-70 and 73 of the application are currently being appealed

**GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

The grounds of rejection to be reviewed on appeal are as set forth in the Appeal Brief, namely:

1. Whether claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are unpatentable under 35 USC 103(a) over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter “Ren”), in view of *Viera*, U.S. Patent 6,039,699?

2. Whether claims 12, 17, 60 and 65 are unpatentable under 35 USC 103(a) over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184?

3. Whether claims 14 and 52 are unpatentable under 35 USC 103(a) over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105?

## ARGUMENT

The following arguments are in response to the particular issues raised by the examiner in the Examiner's Answer, and so should be read in view of that document and together with the Appeal Brief.

The Examiner raises, in three consecutive paragraphs of the Examiner's Answer, three consecutive arguments. First, that creating the catheter of Viera using the metallic materials of Ren using adhesive, welding, brazing or soldering as taught by Viera would create the claimed structure. Second, that one would use the polymeric coextrusion technique taught in Viera with the metals of Ren. And third, that creating the catheter of Viera using the metallic materials of Ren, including the outer layer smoothly tapering to nothing as shown, for example, in Figure 3 of Ren is possible. Appellants will address each argument in turn.

Claim 1 recites "[a] composite medical device produced by a process comprising: constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion..." This claimed process produces a structure distinct from that which would be produced using adhesive, welding, brazing or soldering as taught by Ren. The claimed process produces a continuous metallic bond between the inner and outer portions. As described in the specification on page 8, line 27, "such unitary construction allows the formation of a composite shaft 110 that can be co-drawn and straightened such that the inner portion 112 and the outer portion 114 are formed together as one unitary construction." In contrast, the processes of Viera are all processes where there are discrete bonds that do not result in a continuous bond along the length of the contact between the inner and outer members.

Therefore, when the Examiner writes, "[i]n the Appeal Brief on page 11, appellant states that adhesive, welding, brazing or soldering as taught by Viera (Col.4 lines 26-29) would not result in the proper attachment to create a unitary structure," the examiner, by slightly misquoting the line, substantially alters the argument. What appellants wrote is "The mere substitution of the metallic materials of Ren, with the joining methods taught by Ren of adhesive, welding, brazing or soldering, would not produce the *claimed structure*."Page 11 (italics added). Appellants do not address in the Appeal Brief (nor do we do so here) what is or is not a unitary structure. What appellants point out is that the claim language recites a specific process that results in a specific structure. This structure is the particular unitary structure described in the

specification with the metallic bond discussed above. This structure is simply not present in a catheter where the inner and outer members are attached using adhesive, welding, brazing or soldering as described by Viera.

The Examiner also notes that "Appellant's specification states that suitable attachment techniques to create a unitary structure can include extrusion, adhesive bonding, welding and soldering." This statement contains two errors important to this discussion. First, these attachment techniques are not described as producing a unitary structure as claimed. The words used are "securely connected." Page 8, line 31-page 9, line 1. Appellants have never asserted that all securely connected inner and outer members anticipate the structure covered by the claim. Second, these attachment methods pertain to "other embodiments." Page 8, lines 29-30. The structure claimed is described in the first part of this paragraph (page 8, lines 23-29) and the description in the first part of this paragraph cannot be fairly read to apply to the other embodiments described later.

It can therefore be seen that one cannot produce the claimed structure by modifying Viera using the metallic materials of Ren together with the attachment techniques of Ren. This leads to the second argument in the Examiner's Answer, that that one would use the polymeric coextrusion technique taught in Ren with the metallic materials of Viera.

In this Reply Brief, Appellants will not repeat the arguments made in the Appeal Brief that one would not attempt to use the polymeric extrusion process of Ren to produce a metallic catheter without impermissible hindsight; instead, Appellants confine themselves to the point raised by the Examiner in the Reply Brief: "One of ordinary skill looking to replicate Ren et al would see the co-extrusion method used to join the first and second layers (at no point in this paragraph are polymers and metals mentioned, only the properties of the desired layers) and would apply a co-extrusion method to the materials being used."

One can make such an argument only by ignoring the teachings of Ren in the specification as a whole, the teachings of Viera and the knowledge available to one of skill in the art. The paragraph cited follows one which describes "[m]aterials suitable for use with the present invention." Apart from the stiffening sleeve 38, which can correspond to neither the inner nor outer layer, nothing but various polymers are mentioned. Col. 4, lines 43-59. The outer layer 36 is also described as being "preferable formed of a second material different from the first material. By different material, it is meant *any polymer*...relative to the *other polymer*."

Col. 3, lines 20-24. In light of the specification as a whole, which mentions only polymers as the inner and outer layers, that the paragraph cited by the Examiner does not discuss the materials of the catheter yet again is not an ambiguous omission that leaves the co-extrusion process open to materials other than polymers. It is clear that Viera is discussing a polymeric extrusion process. (See also the last line of that paragraph: "Another method utilizes a shrink wrap material for the outer layer." Col. 5, lines 7-8. Shrink wrap is used, so far as Appellants are aware, exclusively with polymeric materials.)

Viera, which teaches metal layers, teaches common metal fastening techniques: adhesive, soldering, welding, and brazing. These, together with using mechanical fasteners such as screws, Appellants take to be the common metal fastening techniques known to those of skill in the art. All of these techniques can be done with a minimum of common equipment. Metal extrusion, in contrast, requires a substantial amount of equipment. Therefore, even if one were to read the polymeric extrusion process of Ren more broadly than is warranted by the specification, one still would not use a co-extrusion technique to fasten metallic layers, apart from impermissible hindsight.

The third argument is that creating the catheter of Viera using the metallic materials of Ren, including the outer layer smoothly tapering to nothing as shown, for example, in Figure 3 of Ren is possible. Appellants raised this point, not because a tapered transition is claimed in an independent claim in the present application (though it is in a dependent claim), but because, if one were to modify Ren in view of Viera, as the Examiner asserts is obvious, one would keep this feature of Ren, which is in all embodiments described in the specification. The Examiner cites two patents, U.S. Patent Nos. 3,422,648 and 5,557,962, which show tapers created on metal objects. These references do not show the type of taper which Appellants asserted, and maintain, is effectively impossible using a metallic extrusion technique. The taper shown in Ren is a very gradual taper which terminates the distal end of the outer layer. The closest the '962 reference appears to come is in figure 10, which shows a piece that transitions from a circular profile to a square profile. What appears to be a tapering outer layer is rather the diminishing remnants of the circular profile, as is clear from Figs. 10a-10d. The closest the '648 reference appears to come is in Figure 21, where a taper from a first thickness to a second thickness is shown. Neither reference teaches the type of taper shown in Ren and which applicants do not believe can be effectively fashioned using a metal extrusion process. Applicants maintain that modifying

Ren in view of Viera as suggested is not obvious because there is no reasonable expectation of success.

For the reasons stated above and in the Appeal Brief, claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are patentable over Ren et al. in view of Viera, claims 12, 17, 60 and 65 are patentable over Ren and Vera as applied to claims 1 and 57 and further in view of O'Brien et al., and claims 14 and 52 are patentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al. The rejection should therefore be overruled.

Respectfully submitted,  
STEVEN E. WALAK

By his Attorney,

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